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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,783	PAIRET ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/093,240.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *August 25, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application is a continuation of 10/093240, filed March 7, 2002, now abandoned, which claims benefit of provisional application 60/281857, filed April 5, 2001 and also claims benefit of foreign application DE10110772.2-01, filed March 7, 2001. Claims 1-18 are pending in this application and examined on the merits herein. Applicant's preliminary amendment, filed January 26, 2004, in which new claims 14-18 are introduced, is acknowledged.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/093240, filed on March 7, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite a number of chemical names, including Bay-198004, CP-325366, BY343, D-4396, V-11294A, and AWD-12-281. These names are not standard chemical or trivial names and do not clearly and

definitely identify which compounds are indicated, thereby rendering the claims indefinite.

Claims 9 and 10 contains the trademark/trade name Ariflo®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular pharmaceutical compound and, accordingly, the identification/description is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising an anticholinergic such as tiotropium, oxitropium, or ipratropium, and a specific PDE-IV inhibitor described in the art to be useful for the treatment of obstructive pulmonary disease, such as theophylline or cilomilast (Ariflo®), does not reasonably provide

enablement for a combination of **1** with any PDE-IV inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a pharmaceutical composition comprising two pharmaceutical compounds, one being an anticholinergic agent, and the other being a PDE-IV inhibitor, or a method of using the composition to treat an inflammatory or obstructive disease of the respiratory tract. Note that merely possessing two compounds does not enable one skilled in the art to produce a pharmaceutical composition comprising the two compounds in the absence of a motivation to combine them, such as the reasonable expectation that both compounds will be useful for treating the same condition and will produce at least an additive effect when administered together.

The state of the prior art: The anticholinergic agent **1** is known to be useful for the treatment of obstructive pulmonary diseases. A number of selective PDE-IV

inhibitors are also known to be useful for the same purpose, for example a number compounds of formula **2a,** or pharmaceuticals such as enprofylline or roflumilast. According to PCT international publication WO03/011274 (reference included with PTO-892) the human PDE-4 enzyme exists in at least two distinct forms possessing different biological activity. Thus different PDE-4 inhibitors are expected to possess different biological activities depending on their relative affinities for the different forms of PDE-IV.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: As there exist more than one form of the PDE-4 enzyme, there similarly exist more than one type of PDE-4 inhibitor. Thus PDE-4 inhibitors are expected to possess differing activities, and to be individually more or less suitable for the treatment of obstructive pulmonary disease.

Furthermore, synergistic effects and other drug-drug interactions are not expected to be uniformly consistent across all combinations of an anticholinergic compound with any PDE-4 inhibitor. Avery's Drug Therapy, 3rd edition, states that, "Pharmacokinetic interactions observed *in vitro* or in animals will not necessarily occur in man," "Interactions will not necessarily occur in all patients receiving a given combination of drugs known to have a potential for interaction in man," and "Many clinically important interactions, especially those of a pharmacokinetic nature, depend on a variety of factors additional to the drugs given." (Chapter VIII, p. 255, Synopsis of Important Principles, no. 4-6) Although the cited text deals primarily with adverse drug-drug interactions, beneficial drug-drug interactions function in a similar manner

according to similar mechanisms. Thus the determination of every possible interaction between two broad classes of drugs is expected to be highly unpredictable, especially when one of the drugs being combined has properties which are unpredictable to begin with.

The Breadth of the claims: The term PDE-IV inhibitor as it appears in claim 1 is interpreted to mean any compound capable of inhibiting any form of PDE-4. This includes compounds which are not selective for one subtype of PDE-4 over the other, as well as those which possess significant activity against other phosphodiesterase enzymes.

The amount of direction or guidance presented: No direction or guidance is provided to inform one skilled in the art as to the full extent of compounds which are PDE-4 inhibitors, or to the extent of PDE-4 inhibitors which are useful in the claimed invention. No general guidelines are given for the discovery of novel PDE-4 inhibitors or for predicting their subtype selectivity or other interactions with anticholinergics. A number of PDE-4 inhibitors are described as preferred embodiments of the invention but they are not limiting.

The presence or absence of working examples: No working examples are presented of the actual therapeutic efficacy of any of the claimed combinations.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as drug-drug interactions of novel compounds. See MPEP 2164.

The quantity of experimentation necessary: According to the Chemical Abstracts Service 2006 catalog, the Chemical Abstracts Registry contains entries for approximately 26 million organic and inorganic substances, all of which are potentially involved in the claimed method if they happen to possess allosteric MMP-13 inhibitory activity. The Sigma-Aldrich Rare Chemical Library contains over 80000 compounds, all of which are commercially available and also potential candidates for use in the claimed invention. The total number of compounds known either (a) to be PDE-4 inhibitors or anticholinergics or (b) to not be PDE-4 inhibitors or anticholinergics is merely an insignificant fraction of the total number of compounds whose PDE-4 inhibitory or anticholinergic activity or lack thereof is not known. The existing literature does not identify any general method by which inhibitors of PDE-4 and anticholinergics can be identified across all classes of molecular entities claimed other than by synthesizing and testing each one. In order to practice the invention with the full range of PDE-4 inhibitors and anticholinergics beyond the limited number disclosed in the specification, one skilled in the art would be required to undertake a full-scale, high-throughput drug discovery program to discover the additional PDE-4 inhibitors and anticholinergics not specifically recited in the specification.

In the process of screening the extensive number of compounds required to practice the claimed invention, one would be forced to synthesize said molecules. As no synthetic procedures are described and no references cited that teach synthetic protocols to synthesize PDE-4 inhibitors, anticholinergics, or potential lead compounds which may be PDE-4 inhibitors or anticholinergics, other than the admittedly incomplete

list of examples, one wishing to practice the invention would be forced to design novel synthetic pathways. Since synthesis of organic small molecules is complex, the entire scope of claimed molecules cannot be synthesized by simple variations on a core synthetic scheme. In fact, current knowledge of the field of organic synthesis is far from complete, as evidenced by the fact that many synthetic schemes are still considered to be sufficiently novel to be patented, as evidenced by US patents 6500954, 6500955, and 6500972, all of which relate to synthetic methods. Since no structural limitations are given to the claimed invention, the list of compounds to be synthesized would include an enormously diverse set of structures and require an equally diverse array of synthetic procedures to produce them. Thus one of skill in the art would be forced to invest a considerable amount of time and effort devising chemical syntheses spanning all fields of organic, inorganic, and biological chemistry.

In addition to synthesizing candidate compounds and carrying out *in vitro* studies on the molecular target, one wishing to use any of these compositions in a therapeutic method would also be required to undertake *in vivo* tests in animal models of obstructive pulmonary disease in order to determine the presence or absence of a synergistic effect. Animal experiments include, along with the actual induction of disease state, administration of the potential pharmaceutical compound, and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Because of the unpredictability of the art and the lack of any generalized method for

predicting the pharmacological properties of any arbitrarily chosen molecule, these animal experiments would need to be repeated thousands of times, and involve the maintenance, killing, and disposal of at tens of thousands of experimental animals at minimum, to establish the suitability or lack thereof for each compound found to possess the desired activity *in vitro*.

The sort of industrial-scale interdisciplinary drug discovery program described in the preceding paragraphs would present an undue amount of experimentation to require of anyone wishing to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the broad scope of the claims and the lack of guidance from Applicant's disclosure, Applicants fail to provide information sufficient to practice the claimed invention for all possible PDE-4 inhibitors and anticholinergics.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Chambers et al. (PCT international publication WO01/57025, reference included with PTO-1449) Chambers et al. discloses a number of compounds. (pp. 27-31) These compounds are PDE4 inhibitors useful, either alone or in combination with another active agent, for the treatment of asthma and COPD. (p. 33, line 25 – p. 34, line 15) The additional therapeutic agent may be an anticholinergic agent such as ipratropium, tiotropium, or oxitropium bromide. (p. 116, lines 31-33) This combination is a pharmaceutical composition comprising an anticholinergic and a PDE-4 inhibitor according to instant claims 1-8. Chambers et al. thus anticipates these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disse et al. (Reference included with PTO-892) in view of Torphy et al. (Reference included with PTO-892) Disse et al. discloses that tiotropium is useful as a therapeutic agent for the treatment of asthma (p. 460, Table 2, third paragraph) and chronic obstructive pulmonary disease. (p. 461, second paragraph) For the treatment of

asthma, tiotropium bromide was administered in a dose of 10, 40, or 80 μg as a powder in a dry powder inhaler with lactose as an excipient. (p. 460, second paragraph) For the treatment of COPD, tiotropium bromide was administered similarly in a dose of 10, 20, 40, or 80 μg. (p. 461, first paragraph) Another group of patients with COPD was administered tiotropium bromide daily for 28 days with similar results maintained over the course of the study. (pp. 462, table V) Disse et al. does not disclose a pharmaceutical composition comprising tiotropium bromide and a PDE4 inhibitor as described by instant claims 1-13.

Torphy et al. discloses that cilomilast (Ariflo™) is a PDE4 inhibitor which is useful for the treatment of asthma and COPD. (p. 132, right column, second paragraph – p. 134, right column, second paragraph) The dosage given in this study ranged between 2 and 20 mg.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine tiotropium bromide and cilomilast to make a pharmaceutical composition suitable for the treatment of asthma and COPD as disclosed in instant claims 1-3 and 5-10, or two separate formulations as disclosed in instant claim 4. It would also have been obvious to combine the two drugs in a ratio of between 1:250 and 40:1 as disclosed in instant clams 11-12 in a form suitable for inhalation as disclosed in instant claim 13. One of ordinary skill in the art would have been motivated to combine the two compounds because they both treat asthma and COPD by different mechanisms and are thus expected to produce at least additive effects. One of ordinary skill in the art would have been motivated to combine the drugs in a ratio of between 1:250 and 40:1

because combining 80 μg of tiotropium bromide (the most effective does in the results of Disse et al.) and 15 mg cilomilast (the most effective tolerated dose of Torphy et al.) produces a ratio of 1:187.5, which falls within the range of instant claims 11-12. One of ordinary skill in the art would have been motivated to prepare the composition in a formulation suitable for inhalation because Disse et al. already discloses the administration of tiotropium bromide by inhalation. One of ordinary skill in the art would reasonably have expected success because combining known active agents and adjusting details of dosage and route of administration are well within the ordinary and routine level of skill in the art. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being obvious over Disse et al. (reference included with PTO-892) in view of Hoffman et al. (US patent 6417190, reference cited in PTO-892) further in view of Chambers et al. (PCT international publication WO01/57025, reference included with PTO-1449) The disclosure of Disse et al. is described above. Disse et al. does not disclose a pharmaceutical composition comprising tiotropium bromide and a PDE4 inhibitor as described in instant claims 1-16 or a method of treating asthma or COPD as described in instant claims 17-18.

Hoffman et al. discloses a number of compounds having the structure **2a** as disclosed in instant claims 9, 10, and 14, along with PDE4 inhibitory activity. (column 2, line 7- column 3, line 21) Specific compounds disclosed by Hoffman et al. include the compounds disclosed in table I of Hoffman et al. (column 4, lines 37-66) These compounds are useful in the treatment of various diseases including asthma and COPD. (column 4, lines 22-26) A therapeutically effective daily dose of the compounds of Hoffman et al. is preferably between 10 and 300 mg.

The applied reference (Hoffman et al.) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The disclosure of Chambers et al. is discussed previously.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a tiotropium bromide active agent as disclosed by Disse et al. with a PDE4 inhibitor as disclosed by Hoffman et al. to produce the pharmaceutical compositions of instant claims 1-10. It would also have been obvious to prepare the composition with a ratio of anticholinergic:PDE4 inhibitor of between 40:1 and 1:250 as disclosed in instant claims 11-12 and 15-16, and as an inhalable powder with lactose as an excipient as disclosed by instant claims 13-16. It would also have been obvious to administer this composition in a method of treating asthma or COPD as disclosed by instant claims 17-18.

One of ordinary skill in the art would have been motivated to combine the two compounds because both compounds are taught in the prior art as being useful for treating the same disorders by different mechanisms, and are thus expected to produce at least additive effects. One of ordinary skill in the art would have been motivated to combine them in a ratio of between 40:1 and 1:250 because using a dose of 80 μg of tiotropium bromide as disclosed by Disse et al. and a dose of between 10 and 20 mg of PDE4 inhibitor which is within the range disclosed by Hoffman et al., leads to a ratio of between 1:125 and 1:250, which falls within the ranges of instant claims 11-12 and 15-16. One of ordinary skill in the art would have been motivated to produce this composition as a lactose-based inhalable powder because Disse et al. discloses that tiotropium bromide may be administered in this manner and Chambers et al. discloses that a PDE4 inhibitor may be administered in this manner. One of ordinary skill in the art would have been motivated to administer this powder to treat asthma of COPD

because both active ingredients are disclosed in the prior art to be useful for treating these diseases.

One of ordinary skill in the art would reasonably have expected success in combining the compounds and using them to treat asthma and COPD because these compounds were already known to be individually useful for this purpose. One of ordinary skill in the art would have reasonably expected success in preparing the composition as a lactose-containing inhalable powder with the indicated dosage ratio because determining the exact details of dosages and routes of administration are well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-10, and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, and 13 of copending Application No. 10/614365 (Cited in PTO-892, herein referred to as '365). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '365 anticipate those of the present application.

Claims 1-5 of '365 are drawn to a combination of an anticholinergic and a PDE4 inhibitor, anticipating instant claims 1-4 and 7-8. Claims 6-7 of '365 are drawn to combinations of an anticholinergic with a specific PDE4 inhibitor identical to those recited in instant claims 9-10. Claims 12-13 of '365 are drawn to a pharmaceutical composition of an anticholinergic and a PDE4 inhibitor in a form suitable for inhalation as disclosed in instant claim 13. Thus claims 1-8, 12, and 13 of '365 anticipate instant claims 1-4, 7-10, and 13.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-10, and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, and 11-12 of copending Application No. 10/891562 (Cited in PTO-892, herein referred to as '562). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '562 anticipate those of the present application.

Claims 1-3 of '562 are drawn to a combination of an anticholinergic and a PDE4 inhibitor, anticipating instant claims 1-4 and 7-8. Although these claims do not specifically mention an anticholinergic agent the structure recited by claim 1 of '562 is an anticholinergic, as attested by the specification of '562, (p. 1, lines 23-25) Claims 4-7 of '562 are drawn to combinations of an anticholinergic with a specific PDE4 inhibitor selected from a list including enprofylline, roflumilast, and cilomilast, which are all among the PDE4 inhibitors recited in instant claims 9-10. Claims 11-12 of '562 are drawn to a pharmaceutical composition of an anticholinergic and a PDE4 inhibitor in a form suitable for inhalation as disclosed in instant claim 13. Thus claims 1-7, and 11-12 of '562 anticipate instant claims 1-4, 7-10, and 13.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-10, and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 12 of copending Application No. 10/891551 (Cited in PTO-892, herein referred to as '551). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '551 anticipate those of the present application.

Claims 1-3 of '551 are drawn to a combination of an anticholinergic and a PDE4 inhibitor, anticipating instant claims 1-4 and 7-8. Although these claims do not specifically mention an anticholinergic agent the structure recited by claim 1 of '551 is an anticholinergic, as attested by the specification of '551, (p. 1, lines 24-35) Claims 4-6

of '551 are drawn to combinations of an anticholinergic with a specific PDE4 inhibitor selected from a list including enprofylline, roflumilast, and cilomilast, which are all among the PDE4 inhibitors recited in instant claims 9-10. Claim 12 of '551 is drawn to a pharmaceutical composition of an anticholinergic and a PDE4 inhibitor in a form suitable for inhalation as disclosed in instant claim 13. Thus claims 1-6 and 12 of '551 anticipate instant claims 1-4, 7-10, and 13.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/23/06

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